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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/633,345

08/01/2003

Victor Selig

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22203

7590

12/14/2006

EXAMINER

JOHNSON, EDWARD M

KUSNER & JAFFE

HIGHLAND PLACE SUITE 310

6151 WILSON MILLS ROAD

HIGHLAND HEIGHTS, OH 44143

ART UNIT

PAPER NUMBER

1754

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

4

<b>Office Action Summary</b>	<b>Application No.</b> 10/633,345	<b>Applicant(s)</b> SELIG ET AL.	
	<b>Examiner</b> Edward M. Johnson	<b>Art Unit</b> 1754	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 27 November 2006.

2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1 and 3-6 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1 and 3-6 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All    b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____	6) <input type="checkbox"/> Other: _____

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**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 4-6 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Halstead et al. US 6,919,057.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 4, Halstead '057 discloses a method of cleaning and disinfection of devices comprising:

- a) placing the items into a rack within a container having sealing members, a cavity, and a gasket assembly comprising fluid access ports in the form of slots (abstract, Figures),
- b) placing the container into a reprocessor (abstract), thus engaging the ports,
- c) pumping a reprocessing liquid through the slots to contact all surfaces of the device with the liquid (abstract),
- d) removing the rack and container from the reprocessor (see column 11, lines 31-34), which would inherently store the items therein until removed.

When the examiner has reason to believe that the functional language asserted to be critical for establishing novelty in claimed subject matter may in fact be an inherent characteristic of the prior art, the burden of proof is shifted to Applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied upon. In re Fitzgerald et al. 205 USPQ 594. As a practical matter, the Office is not equipped to manufacture or obtain products and make resulting comparisons with the claimed invention. Where, as here, the burden has been shifted to applicant, it is appropriate to make a rejection based upon §102 as well as §103.

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Regarding claim 5, Halstead '057 discloses liquid (abstract).

Regarding claim 6, Halstead '057 discloses a heated air-drying step (see column 12, lines 10-13).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halstead '057.

Regarding claim 1, Halstead '057 discloses a method of cleaning and disinfection of devices comprising:

a) placing the items into a rack within a container having a cavity and a gasket assembly comprising fluid access ports in the form of slots (abstract, Figures),

b) placing the container into a reprocessor, thus engaging the ports,

c) pumping a reprocessing liquid through the slots to contact all surfaces of the device with the liquid (abstract),

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d) removing the rack and container from the reprocessor (see column 11, lines 31-34), which would store the items therein until removed.

Halstead fails to disclose causing the container to assume the closed position at removal.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to cause the container of Halstead to assume the closed position because Halstead discloses a leak test after reprocessing to ensure an endoscope is not damaged during reprocessing (see column 12, lines 27-30), which would motivate an ordinary artisan to close to container upon the disclosed removal of the container to advantageously avoid damage of the item to be reprocessed.

Regarding claim 2, Halstead '057 discloses removing the rack and container from the reprocessor (see column 11, lines 31-34), which would store the items therein until removed.

Regarding claim 3, Halstead '057 discloses a heated air-drying step (see column 12, lines 10-13).

#### ***Response to Arguments***

5. Applicant's arguments filed 11/27/06 have been fully considered but they are not persuasive.

It is argued that as the Examiner well knows... microbial deactivation system. This is not persuasive because Applicant

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does not claim a method wherein the items are exposed to no "airborne bio-contaminants in the surrounding atmosphere." In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a method wherein the items are exposed to no "airborne bio-contaminants in the surrounding atmosphere.") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, '988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is argued that Halstead et al. '057 discloses... automated reprocessor. This is not persuasive because Halstead discloses the container having sealing members (see Fig. 3 and column 6, lines 1-7). It is also noted that apparatus limitations are not generally given undue weight in method claims.

It is argued that Halstead et al. '057 does not teach... as required by claim 4. This is not persuasive because Applicant appears to admit that the container is "closed" when an endoscope is placed within, which would be considered to be a normally closed position rather than an abnormally closed position. Further, it is again noted that apparatus limitations are not generally given undue weight in method claims.

It is argued that Applicants respectfully submit that when Applicants referred to a container being closed above... gasket assembly of the container. This is not persuasive because it would have been obvious to one of ordinary skill in the art at the time the invention was made to close the gasket assembly of the container in view of Halstead's teaching of closing the container, which Applicant appears to admit is disclosed in the cited prior art.

It is argued that claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Halstead et al. '057. This is not persuasive because Halstead discloses placing the items into a rack within a container having a cavity and a gasket assembly comprising fluid access ports in the form of slots (abstract, Figures), and pumping a reprocessing liquid through the slots to contact all surfaces of the device with the liquid (abstract), which would obviously, to one of ordinary skill, at least suggest engaging the fluid ports so as to pump the reprocessing liquid through the slots.

It is argued that further, Halstead et al. '057 does not teach... claim 1 of the present application. This is not persuasive because it would have been obvious to one of ordinary skill in the art at the time the invention was made to cause the container of Halstead to assume the closed position because



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Halstead discloses a leak test after reprocessing to ensure an endoscope is not damaged during reprocessing (see column 12, lines 27-30), which would motivate an ordinary artisan to close to container upon the disclosed removal of the container to advantageously avoid damage of the item to be reprocessed.

It is argued that the Examiner states that "it would have been obvious... assume the closed position..." This is not persuasive because Halstead discloses not damaging the endoscope. And, in any case, Applicant does not claim a method wherein such damage is avoided. It is noted that the features upon which applicant relies (i.e., a method which avoids damage an endoscope or other items inside the claimed container) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

#### **Conclusion**

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward M. Johnson whose telephone number is 571-272-1352. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley S. Silverman

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can be reached on 571-272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Edward M. Johnson  
Primary Examiner  
Art Unit 1754

EMJ